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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,944	03/22/2001	Keith D. Allen	R-654	8251

26619 7590 06/17/2003

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[REDACTED] EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
1636	18

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/815,944	ALLEN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Celine X Qian	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 May 2003.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 11-16,22-26,28-30,32,33 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 11-16 and 22-25 is/are withdrawn from consideration.
- 5) Claim(s) 32 and 33 is/are allowed.
- 6) Claim(s) 26,28,29,30 and 35 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 11-16, 22-26, 28-30, 32, 33 and 35 are pending in the application. Claims 27, 31 and 34 are cancelled. Claims 11-16 and 22-25 are withdrawn from consideration for being directed to non-elected subject matter. Claims 26, 28-30, 32, 33 and 35 are currently under examination.

This Office Action is in response to the Amendment filed on 5/23/03.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/23/03 has been entered.

***Response to Amendment***

The rejection of claims 26, 28-30, 32, 33 and 35 under 35 U.S.C. 112 1<sup>st</sup> paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claim 26 under 35 U.S.C. 112 2<sup>nd</sup> paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 26, 28, 29 and 35 under 35 U.S.C. 102 (b) has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 26, 28, 29 and 35 under 35 U.S.C. 103(a) is maintained for reasons set forth of the record mailed on 11/19/02 and further discussed below.

Claim 30 is rejected under 35 U.S.C. 112 2<sup>nd</sup> paragraph for reasons discussed below.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 28, 29 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mansour et al (1988, Nature, vol. 336, No. 24, 348-352), in view of Mountjoy et al. (1992, Science vol. 257, 1248-1251) and Adachi et al (1999, J. Immunology, vol. 163: 3363-3368).

In response to the rejection, Applicant argue that the references fail to teach or suggest how to generate a disruption in the specific gene of the instant invention and do not teach or suggest that MC1-R knockout mice would exhibit hyperactivity. Applicant therefore concludes that the combined references do not teach or suggest all the claim limitation and the claims are not obvious.

Applicant's arguments have been fully considered but they are not persuasive. The teachings of the references are discussed in detailed in the previous office action mailed on 11/19/02. The combined teaching of the references gives motivation and reasonable expectation of success to make a MC1-R knockout construct to subsequently generate a knockout mouse

Art Unit: 1636

study the function of this gene (see detailed discussion in previous office action). As discussed in the previous office action, the recitation of “wherein the construct, when introduced into a murine embryonic stem cell, results in a transgenic mouse . . .” defines the intended use of the knockout construct, which does not carry patentable weight. Consequently, the phenotype of the mouse is not unexpected results, and the combined teaching of the references meets all the claim limitation. Therefore, the obviousness rejection is maintained.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: breeding the heterozygous transgenic mouse to obtain homozygous transgenic mouse.

***Conclusion***

Claims 32 and 33 are allowed.

Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.  
June 13, 2003

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D  
PRIMARY EXAMINER